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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, and NEW YORK STATE, *ex rel.* [UNDER SEAL],	Case No. CV 17-6356
Plaintiffs,	COMPLAINT FOR VIOLATIONS OF FEDERAL CIVIL FALSE CLAIMS ACT [31 U.S.C. §§ 3729, *et seq.*] and NEW YORK FALSE CLAIMS ACT [N.Y. Finance Law §§ 187, *et seq.*]
vs.	
	JURY TRIAL DEMANDED
[UNDER SEAL],	
Defendants.	**(FILED *IN CAMERA* AND UNDER SEAL)**
	COGAN, J.

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Attorney for Plaintiff-Relator Rad Claim, LLC

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, and NEW YORK STATE *ex rel.* RAD CLAIM, LLC, Plaintiffs, vs. RADIATION THERAPIST ASSOCIATES, P.C., LEADING EDGE RADIATION ONCOLOGY SERVICES, PLLC, PET-CT RADIOLOGY, PLLC, M-LEROS, LLC, SAMEER RAFLA-DEMETRIOUS, M.D., HOSNY SELIM, M.D., KAPILAGAURI PARIKH, M.D., MOUNZER TCHELEBI, M.D., HANI LAMEI ASHAMALLA, M.D., BAHAA EL SAYED MOKHTAR, M.D., and NEWYORK-PRESBYTERIAN/BROOKLYN METHODIST, Defendants.	Case No. _____ COMPLAINT FOR VIOLATIONS OF FEDERAL CIVIL FALSE CLAIMS ACT [31 U.S.C. §§ 3729, *et seq.*] and NEW YORK FALSE CLAIMS ACT [N.Y. Finance Law §§ 187, *et seq.*] JURY TRIAL DEMANDED **(FILED *IN CAMERA* AND UNDER SEAL)**

Plaintiff-Relator Rad Claim, LLC, through its attorneys of record, on behalf of the United States of America and New York State, for its Complaint against Defendants Radiation Therapist Associates, P.C. ("RTA"), Leading Edge Radiation Oncology Services, PLLC ("LEROS"), PET-CT Radiology, PLLC ("PET-CT"), M-LEROS, LLC ("M-LEROS"), Sameer

Rafla-Demetrious, M.D., Hosny Selim, M.D., Kapilagauri Parikh, M.D., Mounzer Tchelebi, M.D., Hani Lamei Ashamalla, M.D.; Bahaa El Sayed Mokhtar, M.D. ("Individual Defendants") and NewYork-Presbyterian/Brooklyn Methodist ("Methodist") (collectively, "Defendants"), alleges as follows:

I. NATURE OF THE ACTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and New York State arising from false and/or fraudulent statements, records, and claims made and caused to be made by Defendants and/or their agents, employees and co-conspirators in violation of the Federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729, *et seq.* and the New York False Claims Act ("NYFCA"), N.Y. Finance Law §§ 187, *et seq.*

2. As detailed below, Defendants engaged in a fraudulent course of conduct that, on information and belief, caused substantial losses to the Medicare and Medicaid programs, by inducing the federal and state governments to pay for radiation oncology imaging and therapy services:

(a) that were billed in violation of the federal Physician Self-Referral Law, commonly referred to as the Stark Law (42 U.S.C. § 1395nn; 42 CFR §§ 411.350, *et seq.*) and the analogous physician self-referral law in New York State (N.Y. Public Health Law § 238-a; 10 NYCRR Subpart 34-1);

(b) that were billed in violation of the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b));

(c) that were not supervised as required for reimbursement; and

(d) that were not performed properly or, as required for reimbursement.

On information and belief, these fraudulent practices began prior to 2012 and continued through at least in or about September 2016.

3. The named Individual Defendants were licensed physicians practicing radiation oncology as part of RTA while also being owner-investors, together with Methodist, in LEROS, an entity providing imaging and radiation oncology therapy services. Defendants Rafla, Ashamalla and Selim occupied senior leadership positions in the radiation oncology department at Methodist, while Defendants Parikh, Tchelebi and Mokhtar were all attending radiation oncologists at Methodist. Imaging services provided at LEROS included Positron Emission Tomography ("PET") and X-ray Computed Tomography ("CT"). Radiation therapy services included Intensity Modulated Radiation Therapy ("IMRT"), Image-Guided Radiation Therapy ("IGRT"), Intensity Modulated Arc Therapy ("IMAT") and Three-Dimensional Conformal Radiation Therapy ("3DCRT"). Each represented a different method of delivering radiation for the treatment of cancer patients. The Individual Defendants referred patients to LEROS for the furnishing of imaging and radiation therapy services, which constituted Designated Health Services ("DHS") under the Stark Law. Due to the ownership interests of the Individual Defendants in LEROS, billing those services to Medicare and Medicaid was prohibited under the Stark Law and New York State law. Notwithstanding this fact, the Individual Defendants, with the active participation and agreement of Methodist, knowingly caused those services to be billed by LEROS to Medicare and Medicaid without disclosing these violations of federal and state self-referral laws, compliance with which was a material condition of government payment. This, in turn, resulted in substantial losses to the Medicare and Medicaid programs, in violation of the FCA and NYFCA.

4. Another fraudulent scheme involved the provision and billing of unsupervised

radiation oncology imaging and therapy services at LEROS. Medicare and Medicaid billing rules required, for the protection of the patient and as a condition of payment, that radiation oncology services be directly supervised by a physician. Direct supervision required that the physician be in the office suite and immediately available to provide assistance and direction throughout the performance of the procedure. The radiation oncology services at LEROS, however, frequently were performed without any physician present or immediately available to provide the required supervision. Defendants nonetheless billed those services to Medicare and Medicaid, in violation of the FCA and NYFCA, resulting in substantial losses to those programs.

5. Lastly, Defendants engaged in a fraudulent scheme that involved the billing of radiation oncology services that were not performed as required for reimbursement:

a. IGRT is a form of radiation therapy that utilizes imaging techniques during each treatment session in order to ensure that the radiation is narrowly focused on the intended treatment area. These images may be captured with CT technology. Although Defendants billed for IGRT radiation therapy, the images frequently were not reviewed as required prior to administration of this type of radiation therapy, thereby defeating the purpose of image guidance in administering such therapy. In billing for IGRT without reviewing the images intended to guide such therapy, Defendants effectively sought reimbursement for services not rendered, in violation of the FCA and NYFCA. Doing so placed patients at grave risk because the radiation therapy paid for was not delivered to the appropriate anatomic structures. Thus, patients were told that their diseases had been treated when, in fact, they were not. Thus, malignant

lesions were left untreated (or undertreated) and that fact was concealed from patients.

b. Brachytherapy for prostate cancer is a procedure involving the placement of radioactive seeds in the prostate gland to treat the cancer. On multiple occasions, Defendant Ashamalla improperly performed this procedure by implanting the radioactive seeds either entirely or partially outside the prostate gland and inside the rectum. The services, however, were billed to insurers anyway, including Medicare and Medicaid. Moreover, Defendant failed to comply with federal and state regulations requiring that he report the misadministration of radiation to the government and to the patients who received deficient (*i.e.*, non-therapeutic or sub-therapeutic) treatment.

6. The fraudulent practices described above constituted "false and fraudulent" claims under the FCA and the NYFCA. Such claims cheated the government and unlawfully enriched the Defendants. Therefore, Plaintiff-Relator Rad Claim, LLC, seeks to recover all available damages, civil penalties, and other relief for violations alleged herein.

II. PARTIES

7. Plaintiff-Relator Rad Claim, LLC is a New York limited liability company headquartered on Long Island and formed for the purpose of commencing this lawsuit under the FCA and NYFCA. The sole member of Rad Claim, LLC is a medical professional licensed in New York State with personal knowledge of the facts and circumstances alleged herein ("Person A").

8. Defendant Radiation Therapist Associates, P.C. is a New York professional

service corporation, with a principal business address of 506 6th Street, Brooklyn, New York. Under an agreement with Methodist, RTA supplied all the hospital's radiation oncology services, defined as "all inpatient and outpatient radiation oncology services, studies and procedures," including "without limitation, the provision of patient care and teaching activities."

9. Defendant Leading Edge Radiation Oncology Services, PLLC is a New York professional service limited liability company, with a principal business address of 8715 5th Avenue, Brooklyn, New York. LEROS was a freestanding radiation therapy center that provided radiation imaging and therapy services to patients referred to LEROS from physician practices like RTA, among other referral sources.

10. Defendant PET-CT Radiology, PLLC is a New York professional service limited liability company, with a principal business address of 8715 5th Avenue, Brooklyn, New York. PET-CT was a freestanding imaging center that providing imaging services to patients referred to PET-CT from physician practices like RTA, among other referral sources.

11. Defendant M-LEROS, LLC is a New York limited liability company, with a principal business address of 99-20 4th Avenue, #314, Brooklyn, New York. M-LEROS was a joint venture of LEROS and Methodist.

12. Defendant Sameer Rafla-Demetrious, M.D., resides in Staten Island, New York. Dr. Rafla-Demetrious is a physician licensed to practice in New York State. Dr. Rafla-Demetrious practiced at RTA and held an ownership interest in LEROS.

13. Defendant Hosny Selim, M.D. resides in Port Washington, New York. Dr. Selim is a physician licensed to practice in New York State. Dr. Selim practiced at RTA and held an ownership in LEROS.

14. Defendant Kapilagauri Parikh, M.D., resides in New Jersey. Dr.

Parikh is a physician licensed to practice in New York State. Dr. Parikh practiced at RTA and held an ownership interest in LEROS.

15. Defendant Mounzer Tchelebi, M.D., resides in New York, New York. Dr. Tchelebi is a physician licensed to practice in New York State. Dr. Tchelebi practiced at RTA and held an ownership interest in LEROS.

16. Defendant Hani Lamei Ashamalla, M.D. resides in Port Washington, New York. Dr. Ashamalla is a physician licensed to practice in New York State. Dr. Ashamalla practiced at RTA and held an ownership interest in LEROS.

17. Defendant Bahaa El Sayed Mokhtar, M.D., resides in Staten Island, New York. Dr. Mokhtar is a physician licensed to practice in New York State. Dr. Mokhtar practiced at RTA and held an ownership interest in LEROS.

18. NewYork-Presbyterian/Brooklyn Methodist is a New York not-for-profit corporation with a principal business address of 506 Sixth Street, Brooklyn, New York.

III. JURISDICTION AND VENUE

19. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Relator is the original source of the facts and information alleged in this Complaint. Relator voluntarily provided the information on which its allegations are based to the government before filing this action.

20. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. §

3732(a), because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, Defendants can be found in this District and/or transact business in this District.

21. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a), because Defendants can be found in and/or transact business in this District. At all times relevant to this Complaint, Defendants regularly conducted substantial business within this District, maintained employees in this District and/or could otherwise be found and resided in this District. In addition, statutory violations, as alleged herein, occurred in this District.

IV. APPLICABLE LAW

A. The False Claims Act

22. The FCA was originally enacted during the Civil War and was substantially amended in 1986. Congress enacted the 1986 amendments to enhance and modernize the government's tools for recovering losses sustained by frauds against it. The amendments were intended to create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the government's behalf.

23. The FCA prohibits knowingly presenting or causing to be presented to the federal government a false or fraudulent claim for payment or approval. 31 U.S.C. § 3729(a)(1)(A). Additionally, it prohibits knowingly making or using a false or fraudulent record or statement "material to a false or fraudulent claim" paid or approved by the federal government, or "material to an obligation to pay" money to the government and further prohibits knowingly concealing and improperly avoiding or decreasing "an obligation to pay" money to the government. 31 U.S.C. § 3729(a)(1)(B), (G). Pursuant to 31 U.S.C. § 3729(a)(1)(B), a false or

fraudulent statement or record that is made for the purpose of causing the government to pay a claim, even if the fraudulent statement or record is not proffered directly to the government, is still actionable where there is some nexus between the statement or record and the payment of the claim. Furthermore, both affirmative misrepresentations and the omission of facts material to a governmental decision to pay can render a claim false under the FCA. The FCA also prohibits two or more parties from conspiring to violate any of the liability provisions of the statute. 31 U.S.C. § 3729(a)(1)(C).

24. Any person who violates, or conspires to violate, the FCA is liable for a civil penalty of up to $11,000 per claim for claims made on or after September 29, 1999 (and up to $21,563 per claim for claims made after November 2, 2015), plus three times the amount of the damages sustained by the United States. 31 U.S.C. § 3729(a).

25. The FCA does not require direct contact between a defendant and the government. By its terms, the FCA imposes liability on any person who presents or ***causes*** to be presented a false or fraudulent claim to the government (or false statement in support of a false or fraudulent claim). See 31 U.S.C. § 3729(a).

26. To "cause" an FCA violation, it is not necessary that a defendant's fraudulent conduct be the last in the series of events that results in financial loss to the government. As applied by the courts, the standard for "causation" under the FCA is whether the submission of a false or fraudulent claim was "reasonably foreseeable" from a defendant's actions. Under this standard, a defendant's fraudulent conduct can occur anywhere in the chain of events leading to financial loss by the government, and can be an indirect, as well as direct, cause of the loss. Moreover, the defendant need not be the recipient or beneficiary of the false claim. All that is

required is that the defendant, by its fraudulent conduct, set in motion a series of events which results in a reasonably foreseeable loss to the government.

27. The FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States government provides any portion of the money or property which is requested or demanded, or if the government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

28. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendants during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

29. The NYFCA is modeled after the FCA, and its liability provisions are virtually identical. Similarly to the FCA, any person who violates, or conspires to violate, the NYFCA is liable for three times the amount of the damages sustained by New York State. In addition, a violator faces a civil penalty of up to $12,000 per claim.

B. The Federal Health Care Programs

30. The health care programs described in the paragraphs below, and any other government-funded healthcare programs, shall be referred to as "Federal Health Care Programs."

31. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* ("Medicare") is a health insurance program administered by the United States that is funded by taxpayer revenue. Entitlement to Medicare is based on age, disability or affliction with

certain diseases. The program is overseen by the United States Department of Health and Human Services ("HHS") through the Centers for Medicare and Medicaid Services ("CMS"). Medicare provides for payment of hospital services, medical services, durable medical equipment and prescription drugs on behalf of Medicare-eligible beneficiaries. Medicare will only pay for items and services which are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a).

32. Claims submitted to Medicare for payment, whether submitted on a paper CMS-1500 Claim Form, or electronically, carry certifications of truth and accuracy. The paper Claim Form carries a certification that the billing information on the form is "true, accurate and complete," that the claimant has "familiarized [himself or herself] with all applicable laws, regulations, and program instructions," that the claimant has "provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision," that the claim "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law)" and that the services provided "were medically necessary and personally furnished by" the physician-claimant whose signature appears on the claim form, or that they were "furnished incident to [the physician's] professional service by [the physician's] employee under [the physician's] direct supervision." *See* CMS-1500 Claim Form (Rev. (02-12)). The Claim Form further contains a notice that "[a]ny one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws." Those who submit claims electronically are

likewise required to agree that the claims submitted will be "accurate, complete and truthful" and to "acknowledge that all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim . . . may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law." Medicare Claims Processing Manual, Chapter 24, 30.2.

33. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v ("Medicaid") is a health insurance program administered by the United States and individual states and is funded by federal, state and local taxpayer revenue. The Medicaid Program is overseen by HHS through CMS. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid. The Medicaid program pays for services pursuant to plans developed by the States and approved by HHS through CMS. 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. 42 U.S.C. §§1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily established share of "the total amount expended ... as medical assistance under the State plan." See 42 U.S.C. §1396b(a)(1). This federal-to-state payment is known as Federal Financial Participation.

34. New York maintains a federally-approved Medicaid program to reimburse health care charges made by physicians and other health care providers for the treatment of many low-income New York citizens not covered by Medicare or private insurance. Claims submitted to the New York Medicaid Program cause payments to be made by both the United States and New York State. The United States and New York State contribute approximately half the cost of

each claim submitted to the New York Medicaid Program. Providers apply to participate in the New York Medicaid Program and agree as a condition of both participation and payment to comply with all the policies and procedures of the New York Department of Health ("DOH"), which administers the Medicaid Program in New York State. All claims submitted to the Medicaid Program, whether on paper or electronically, carry a Claim Certification Statement that certifies the provider's agreement to these conditions. The Certification Statement further states that all information included on the claim form is "true, accurate and complete" and that "no material fact has been omitted." New York State Medicaid Program, Information for All Providers, General Billing, pp. 7-8; eMedNY/Medicaid Management Information System, Certification Statement for Provider Billing Medicaid. In addition, the Certification Statement includes an acknowledgement that "payment and satisfaction of this claim will be from federal, state and local public funds and that I may be prosecuted under applicable federal and state laws for any false claims, statements or documents or concealment of a material fact." *Id.*

35. DOH policies and procedures include an explicit exclusion from Medicaid coverage for medical care and services that are "fraudulently claimed" or "represent abuse or overuse," and define as an "unacceptable practice" when a provider "knowingly [makes] a claim for an improper amount or for unfurnished, inappropriate or excessive care, services or supplies." DOH also defines Medicaid fraud to include a provider who "submits false information for the purpose of obtaining greater compensation than that to which he/she is legally entitled." New York State Medicaid Program, Information for All Providers, General Policy, pp. 22-25. DOH further reserves the right to recover any overpayments, including "any amount not authorized to be paid under the Medicaid Program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake." *Id.*

C. **Medicare and Medicaid Reimbursement of Radiation Oncology**

36. Medicare and Medicaid reimburse the radiation oncology imaging and therapy services described in paragraph 3 above, when such services are medically necessary and performed under appropriate supervision. Under Medicare, radiation therapy services and CT imaging services to assist in the accurate placement of radiation fields, when performed in a free-standing radiation therapy center such as LEROS, must be performed under the direct supervision of a physician, which means "the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure." 42 CFR § 410.32(b)(3)(ii); *see* Medicare Benefit Policy Manual, Chapter 13, § 80; Chapter 15, §§ 80, 90; Medicare Physician Fee Schedule assigning Level 2 (Direct Supervision) to CT imaging services. The Medicaid program likewise requires that, in order to be paid for radiation therapy and imaging services, the physician "must supervise and control the radiology technician who performs the radiology procedures." New York State Medicaid Program, Physician Fee Schedule, at p. 484 (2006); *see also* N.Y. Public Health Law § 3501 and 10 NYCRR 89.2 (defining radiation therapy as requiring supervision of a radiation oncologist). The level of required supervision under Medicaid is presumptively the same as under Medicare in the absence of more specific guidance. *See* 10 NYCRR § 86-1.6(a) (except as otherwise provided by regulation or special determination of commissioner, "allowable costs shall be determined by the application of the principles of reimbursement developed for determining payments under the title XVIII (Medicare) program").

37. Claims submitted to Medicare or Medicaid for payment are required to identify the services performed by using codes contained in the American Medical Association's Current Procedural Terminology manual, which are commonly referred to as "CPT" codes. The claims

are also required to reflect, among other things: (a) the diagnosis code (referred to as an "ICD-10" code, formerly referred to as an "ICD-9" code) that accurately identifies the medical diagnosis (*i.e.*, the patient's condition); (b) the date the service was rendered; and (c) the name of the patient who received the service. CMS, through its fiscal intermediaries, determines whether a procedure or service is adequately documented, whether it is medically necessary, whether or not the claim otherwise qualifies for payment and the proper amount of reimbursement.

38. On information and belief, beginning prior to 2012 and continuing through at least in or about 2016, the Individual Defendants submitted and caused the submission of claims to and received reimbursement from Medicare and Medicaid for the radiation oncology imaging and therapy services performed at LEROS and described in paragraph 3 above. The charts below contain information recorded by CMS for 2013 and reflect at least some of the billing and payment information for the identified Individual Defendants. The charts list some of the imaging and radiation codes billed to Medicare, the average charges billed and the average amounts paid on those charges. This data, on information and belief, is ***representative*** of the Medicare billing and payment activities that occurred during the entire period of the alleged fraud:

All Information in the Below Charts is Taken From CMS Medicare Provider Utilization and Payment Data: Physician and Other Supplier CY 2013

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Sameer Rafla-Demetrious, M.D. NPI #1659354918	506 6th Street, Brooklyn, NY	77014	CT scan guidance for insertion of radiation therapy fields	$400	$115

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Sameer Rafla-Demetrious, M.D. NPI #1659354918	506 6th Street, Brooklyn, NY	77263	Management of radiation therapy, complex	$1294	$140
Sameer Rafla-Demetrious, M.D. NPI #1659354918	506 6th Street, Brooklyn, NY	77290	Management of radiation therapy, simulation, complex	$989	$482
Sameer Rafla-Demetrious, M.D. NPI #1659354918	506 6th Street, Brooklyn, NY	77300	Calculation of radiation therapy dose	$210	$58
Sameer Rafla-Demetrious, M.D. NPI #1659354918	506 6th Street, Brooklyn, NY	77301	Management of modulation radiation therapy planning	$3800	$1733
Sameer Rafla-Demetrious, M.D. NPI #1659354918	506 6th Street, Brooklyn, NY	77334	Radiation treatment devices, design and construction, complex	$600	$138
Sameer Rafla-Demetrious, M.D. NPI #1659354918	506 6th Street, Brooklyn, NY	77336	Radiation therapy consultation	$451	$42

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Sameer Rafla-Demetrious, M.D. NPI #1659354918	506 6th Street, Brooklyn, NY	77338	Design and construction of device for radiation therapy	$716	$437
Sameer Rafla-Demetrious, M.D. NPI #1659354918	506 6th Street, Brooklyn, NY	77418	Intensity modulated radiation treatment delivery	$1187	$387
Sameer Rafla-Demetrious, M.D. NPI #1659354918	506 6th Street, Brooklyn, NY	77427	Radiation treatment management, 5 treatments	$717	$157
Kapilagauri Parikh, M.D. NPI #1215911094	506 6th Street, Brooklyn, NY	77014	CT scan guidance for insertion of radiation therapy fields	$393	$115
Kapilagauri Parikh, M.D. NPI #1215911094	506 6th Street, Brooklyn, NY	77290	Management of radiation therapy, simulation, complex	$988	$500

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Kapilagauri Parikh, M.D. NPI #1215911094	506 6th Street, Brooklyn, NY	77300	Calculation of radiation therapy dose	$214	$61
Kapilagauri Parikh, M.D. NPI #1215911094	506 6th Street, Brooklyn, NY	77334	Radiation treatment devices, design and construction, complex	$603	$138
Kapilagauri Parikh, M.D. NPI #1215911094	506 6th Street, Brooklyn, NY	77336	Radiation therapy consultation	$451	$42
Kapilagauri Parikh, M.D. NPI #1215911094	506 6th Street, Brooklyn, NY	77427	Radiation treatment management, 5 treatments	$716	$157
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77014	CT scan guidance for insertion of radiation therapy fields	$600	$115

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77263	Management of radiation therapy, complex	$1300	$134
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77280	Management of radiation therapy, simulation, simple	$650	$170
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77290	Management of radiation therapy, simulation, complex	$1200	$501
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77295	Management of radiation therapy, 3D	$2500	$407
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77300	Calculation of radiation therapy dose	$300	$61

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77301	Management of modulation radiation therapy planning	$3500	$1868
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77315	Isodose radiation therapy plan, complex	$450	$121
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77334	Radiation treatment devices, design and construction, complex	$620	$138
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77336	Radiation therapy consultation	$380	$42
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77338	Design and construction of device for radiation therapy	$1000	$461

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77370	Radiation therapy consultation	$500	$113
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77416	Radiation therapy consultation	$950	$248
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77417	Radiation therapy consultation	$200	$48
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77418	Radiation therapy consultation	$1800	$387
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77427	Radiation treatment management, 5 treatments	$720	$156

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Mounzer Tchelebi, M.D. NPI #1639152960	374 Stockholm Street, Brooklyn, NY	77470	Radiation therapy consultation	$850	$136
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77014	CT scan guidance for insertion of radiation therapy fields	$390	$116
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77263	Management of radiation therapy, complex	$1290	$138
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77280	Management of radiation therapy, simulation, simple	$636	$162
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77285	Management of radiation therapy, simulation, intermediate	$417	$233

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77290	Management of radiation therapy, simulation, complex	$975	$500
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77295	Management of radiation therapy, 3D	$1947	$408
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77300	Calculation of radiation therapy dose	$193	$61
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77301	Management of modulation radiation therapy planning	$3800	$1847
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77315	Isodose radiation therapy plan, complex	$549	$121

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77334	Radiation treatment devices, design and construction, complex	$524	$138
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77336	Radiation therapy consultation	$445	$42
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77338	Design and construction of device for radiation therapy	$714	$462
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77370	Radiation therapy consultation	$561	$113
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77414	Radiation therapy consultation	$779	$248

Provider Name and NPI	**Location**	**Procedure Code**	**Procedure Description**	**Average Medicare Billed**	**Average Medicare Paid**
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77416	Radiation therapy consultation	$967	$249
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77417	Radiation therapy consultation	$198	$14
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77418	Radiation therapy consultation	$1176	$387
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77421	X-ray guidance for radiation therapy delivery	$251	$70
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77427	Radiation treatment management, 5 treatments	$711	$157

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Hani Lamei Ashamalla, M.D. NPI #1467435701	506 6th Street, Brooklyn, NY	77470	Radiation therapy consultation	$1010	$124
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77014	CT scan guidance for insertion of radiation therapy fields	$390	$100
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77263	Management of radiation therapy, complex	$1286	$137
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77290	Management of radiation therapy, simulation, complex	$970	$480

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77300	Calculation of radiation therapy dose	$197	$61
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77301	Management of modulation radiation therapy planning	$3800	$1743
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77315	Isodose radiation therapy plan, complex	$513	$121
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77334	Radiation treatment devices, design and construction, complex	$534	$137

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77336	Radiation therapy consultation	$444	$40
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77338	Design and construction of device for radiation therapy	$713	$433
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77370	Radiation therapy consultation	$563	$113
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77416	Radiation therapy consultation	$951	$248

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77417	Radiation therapy consultation	$198	$14
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77418	Radiation therapy consultation	$1177	$343
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77421	X-ray guidance for radiation therapy delivery	$250	$63
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77427	Radiation treatment management, 5 treatments	$710	$155

Provider Name and NPI	Location	Procedure Code	Procedure Description	Average Medicare Billed	Average Medicare Paid
Bahaa El Sayed Mokhtar, M.D. NPI #1790768034	506 6th Street, Brooklyn, NY	77470	Radiation therapy consultation	$1053	$125

39. The Medicaid Program likewise made payments to LEROS for these same kinds of radiation oncology procedures and issued checks to LEROS on a regular basis, with remittance advice addressed to:

LEADING EDGE RADIATION ONC
LEROS
8715 5th AVE
BROOKLYN NY 11209-5230

40. In addition to the billed services described above, the Individual Defendants submitted and caused the submission of numerous claims to Medicare and Medicaid for diagnostic and surveillance PET/CT scans performed at PET-CT, including claims for CPT 78815 (PET image w/ CT skull-thigh) and CPT 78816 (PET image w/ CT fully body).

D. The Physician Self-Referral Laws

41. Under the Stark Law, a physician may not refer a Medicare patient for a designated health service ("DHS") to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, including certain compensation arrangements and ownership or investment interests, unless an exception applies. 42 U.S.C. § 1395nn(a)(1)(A); (42 CFR §§ 411.350, *et seq.*). DHS includes the imaging and radiation therapy services described

above. The Stark Law also prohibits the entity furnishing the DHS from submitting claims to Medicare as a result of a prohibited referral. 42 U.S.C. § 1395nn(a)(1)(B). No payment may be made for DHS provided in violation of the Stark Law. Furthermore, because the Stark Law is a strict liability statute, the intent or knowledge of the violator is irrelevant to proving liability.

42. Possible sanctions for violating the Stark Law include civil monetary penalties (up to $15,000 for each service improperly claimed and up to $100,000 for each circumvention scheme), Federal health care program exclusion and an assessment of up to three times the amount claimed. 42 U.S.C. § 1395nn(g); 42 U.S.C. § 1320a-7a(a). Claims submitted in violation of the Stark Law, moreover, will create liability under the FCA for any amounts paid by Medicare on those non-reimbursable claims. Additionally, the Stark Law's mandate has been extended, through the FCA, to Medicaid claims based on statutory language denying Federal Financial Participation to States for any claims submitted in violation of the Stark Law. 42 U.S.C. § 1396b(s). Accordingly, Medicaid claims submitted in violation of the Stark Law likewise will create liability under the FCA and NYFCA.

43. New York State enacted its own statute that prohibits referrals for DHS under circumstances which essentially mirror the Stark Law's provisions (N.Y. Public health Law § 238-a; 10 NYCRR Subpart 34-1). The New York law prohibits the submission of claims resulting from prohibited referrals to any payer, public or private, and imposes joint and several liability on the referring and furnishing providers for any amounts collected on such claims. Therefore, Medicaid claims submitted in violation of the New York law will create liability under both the FCA and NYFCA for all amounts paid on those non-reimbursable claims.

44. Under Stark Law regulations, physicians in a group practice, as defined under 42

CFR § 411.352, may refer DHS within the group practice under the in-office ancillary services exception to the Stark Law referral prohibition, provided that all the requirements of that exception, set forth at 42 CFR § 411.355(b), are satisfied. Those requirements include, among other things, that the DHS be furnished either in the same building where the referring physician or group practice regularly furnishes medical services (*see* 42 CFR § 411.355(b)(2)) or in a centralized building that is owned or leased by the group practice for the furnishing of some or all of the DHS provided by the group (*see* 42 CFR § 351). Additionally, the exception requires that the DHS be supervised either by the referring physician, a group practice member or another individual supervised by the referring physician or other physician in the group practice and that the supervision rendered otherwise comply "with all other applicable Medicare payment and coverage rules for the services." 42 CFR § 411.355(b)(1)(iii). The exception also requires that the DHS be billed by (a) the physician performing or supervising the service; or (b) the group practice of which that physician is either a member or a physician in the group under a billing number assigned to the group; or (c) an entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or a billing number assigned to the physician or group; or (d) a third party billing company acting as an agent of the physician, group or entity.

45. Another requirement of the in-office ancillary services exception, for PET/CT imaging services, is that the referring physician must provide written notice to the patient at the time of the referral that the patient may receive the same services from another provider, and must include with the notice a list of five alternative providers within a 25-mile radius of the referring physician's office location or, if fewer than five alternative service providers within that radius exist, the referring physician must provide a list of all such providers.

46. The requirements of the in-office ancillary services exception discussed above are largely, if not entirely, replicated by the New York State self-referral law. *See* NY Public Health Law § 238-a(2)(b).

V. FACTS UNDERLYING THE FRAUD SCHEMES

A. The Fraudulent Scheme to Submit Claims in Violation of the Physician Self-Referral Laws

47. As described above, Defendants were not permitted to bill Medicare or Medicaid for radiation therapy and imaging services in violation of the Stark Law (42 U.S.C. § 1395nn(a)(1); 42 CFR §§ 411.350, et seq.) or its New York State equivalent statute (N.Y. Public Health Law § 238-a; 10 NYCRR Subpart 34-1). Defendants, however, did just that.

48. On information and belief, LEROS was formed in or about 2003 by several of the Individual Defendants, all of whom practice at RTA and are affiliated with the radiation oncology department at Methodist. On information and belief, Defendants Rafla, Ashamalla and Selim held leadership roles in Methodist's radiation oncology department and Defendant Selim was Director of Methodist's radiation oncology residency training program. On information and belief, Methodist substantially capitalized the creation of LEROS, and the Individual Defendants and Methodist shared in the profits generated by LEROS through another entity, M-LEROS, which was formed as a joint venture between Methodist and LEROS.

49. The radiation oncology imaging and therapy services described in paragraph 3 above constituted DHS and were performed at LEROS on patients referred to that facility by RTA and the Individual Defendants. The ownership interests of the Individual Defendants in LEROS, however, created prohibited financial relationships between each of them and LEROS (as the entity furnishing and/or billing the DHS) which rendered those referrals illegal under the Stark Law in the absence of a recognized exception. No such exception existed in this case.

Even assuming that RTA qualified as a group practice under the Stark Law, the in-office ancillary services exception, which might have otherwise protected DHS referrals made within the group, did not apply in these circumstances because: (a) the DHS was not furnished either in the same building in which RTA regularly furnished medical services or in a centralized building owned or leased by RTA for the furnishing of DHS; (b) the DHS typically was not supervised as required under the exception or in accordance with Medicare payment and coverage rules; (c) the DHS was not billed as required under the exception; and (d) in the case of PET/CT scans furnished at LEROS, no notice to patients or list of alternative facilities was provided as required under the exception. No other exception exists under the Stark Law that could protect DHS referrals made by the Individual Defendants to LEROS.

50. The Individual Defendants, on information and belief, were aware that their ownership interests in LEROS prohibited them from billing for the radiation oncology services performed on patients who they referred there, and that no exception permitting such conduct existed. The Individual Defendants nonetheless knowingly submitted and caused the submission of claims to Medicare and Medicaid for radiation oncology services in violation of the Stark Law and the analogous New York State law prohibiting physician self-referrals.

51. On multiple occasions, starting in or about 2012, Person A witnessed Defendant Ashamalla ask for PET/CT reports from LEROS, observe that his name was listed as the ordering physician and then instruct personnel to call LEROS and direct that the ordering physician on the report be changed. On one occasion, Person A overheard a smiling Defendant Ashamalla state in words or substance: "We have to make sure this is corrected. No one can see this. We will get into trouble." Person A witnessed that on some of these occasions, Ashamalla spoke to LEROS personnel directly and on other occasions he directed that others instruct

LEROS personnel to change the ordering physician's name in order to substitute another physician's name for his own. On another occasion, Person A discovered that a patient previously seen by Person A was referred by RTA to LEROS and that the resulting PET/CT test report falsely reflected that the referring physician was a surgeon who had departed Methodist two years earlier and was then practicing in the western United States.

52. It was common for the radiation oncology residents at Methodist who were practicing at RTA under the tutelage of the Individual Defendants, to make comments like "It's all about the money money" and "Cha-Ching," to indicate that the Individual Defendants were motivated by financial considerations in referring patients to LEROS. The residents also advised Person A that they were told to make sure that all patients were referred to LEROS in order to please Defendants Rafla and Ashamalla. Person A also was expected to refer all Person A's patients to LEROS for PET/CT imaging services.

53. Some physicians who referred their patients to RTA became upset when they learned that their names were listed on LEROS PET/CT reports as referring physicians, even though they had not referred their patients to LEROS and actually preferred a different facility. As many as 90-95% of RTA patients were sent to LEROS for PET/CT scans and then for follow-up surveillance PET/CT scans (notwithstanding that continuous follow-up surveillance scans are not in the national cancer guidelines for many cancers).

54. On information and belief, Methodist also was fully aware through, among others, its former President and CEO Mark J. Mundy, its Senior Vice President Errol P. Hankin and its Senior Vice President for Finance Edward Zeidberg, that RTA and the Individual Defendants referred patients to LEROS for the furnishing of DHS and that the Individual Defendants simultaneously held ownership interests in LEROS for which no cognizable exception existed

under the Stark Law or New York State law. Person A knows that frequent meetings were held between the Individual Defendants and Methodist executives, but Person A was not invited to participate in these meetings. Methodist executives also would sometimes attend joint RTA-LEROS events such as holiday and retirement parties. Person A recalls seeing Methodist's former Executive Vice President for Medical Affairs, Stanley Sherbell, M.D., at these events, which generally took place at Byblos Restaurant in Manhattan. Person A recalls that at a retirement party for Defendant Selim held at this restaurant, complete with belly-dancers, a small table was reserved for Methodist executives.

55. On information and belief, Methodist agreed with RTA and the Individual Defendants to submit and cause the submission of claims for DHS services referred by the Individual Defendants and performed at LEROS in violation of the Stark Law and New York State law. In submitting those claims to the Medicare and Medicaid programs, the Defendants knowingly concealed the fact that those claims were not reimbursable because they arose from violations of the physician self-referral laws described above. Compliance with the requirements of those laws was indisputably a condition of payment and highly material to the government's decision to reimburse, given that the Stark Law and analogous New York State law explicitly denied reimbursement for claims arising from illegal self-referrals.

56. Accordingly, all claims submitted and caused to be submitted by the Defendants to Medicare and Medicaid that arose from the undisclosed and illegal self-referrals of the Individual Defendants to LEROS were false claims under the FCA. Moreover, all amounts received and converted by Defendants as a result of these fraudulent claim submissions after the effective date of the Patient Protection and Affordable Care Act ("PPACA") on March 23, 2010, represented "overpayments" that were never repaid and that therefore became "false claims" by operation of

law within the meaning of the FCA and PPACA. 31 U.S.C. § 3729(b)(3); 42 U.S.C. § 1320a-7k(d). As a consequence of this fraudulent scheme, the United States and New York State suffered substantial losses in an amount to be proven at trial.

B. The Fraudulent Scheme to Submit Claims in Violation of the Anti-Kickback Statute

57. A second fraudulent scheme involved submitting and causing the submission of claims in violation of the federal anti-kickback statute ("AKS"), which is codified at 42 U.S.C. § 1320a-7b(b). The AKS, a felony statute, prohibits the offer, receipt, payment or solicitation of any form of remuneration (directly or indirectly, overly or covertly, in cash or in kind) to induce the referral of any individual for the furnishing or any item or service payable under a federal health care program, including Medicare and Medicaid. A "false claim" is defined by statute to include any claim incorporating items or services resulting from a violation of the anti-kickback statute:

> (g) In addition to the penalties provided for in this section [i.e., 42 U.S.C. § 1320a-7b] . . . a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [31 U.S.C. §§ 3729, et seq.]

Defendants violated the AKS in two ways.

58. ***First***, Defendants provided free door-to-door transportation to Methodist patients being treated by the Individual Defendants at RTA by arranging for free taxi service (via Ridge Car Service, 374 86th Street, Brooklyn, NY) from the patient's home to LEROS, where the patients were being referred for radiation imaging and therapy services. The cost for this service was paid either by RTA or LEROS. This free transportation constituted an illegal financial inducement to encourage patient self-referrals to LEROS that was not protected under any AKS safe harbor. Prior to 2017, no safe harbor protected the payment of remuneration in the form of

free or discounted transportation. On January 6, 2017, a new "Local Transportation" safe harbor became effective which exempted from the definition of remuneration "free or discounted local transportation made available by an eligible entity." 42 CFR § 1001.952(bb). However, to comply with the safe harbor, a provider must, among other things, "set forth in a policy" the availability of the transportation, not base availability of the transportation "in a manner related to the past or anticipated volume or value of Federal health care program business," and offer the transportation only to individuals who are "established patients" both of the provider supplying the transportation ***and*** the provider to which the individuals are being transported. *Id.* Here, neither RTA nor LEROS had a written policy describing the transportation service, the service was being offered specifically to facilitate referrals of Medicare and Medicaid business from RTA to LEROS (not to RTA generally) and many of the patients to whom the transportation service was offered were not established patients of LEROS because they had not independently "selected and initiated contact" with LEROS or previously attended appointments at LEROS.

59. ***Second***, Jacqueline Andrews, a Business Manager and Billing Supervisor at PET-CT and LEROS, was paid a commission for each successful referral of a patient to Methodist for the performance of a radiosurgery procedure. LEROS did not offer radiosurgery, and Andrews referred patients who required such services to Methodist and obtained the necessary prior authorization from Medicare, Medicaid or other insurer. Andrews received a 4% commission for each such successful referral based on the amount collected for the services. This was a blatant violation of the AKS, which prohibits the payment of such financial incentives to induce the referral of patients for services reimbursed by any Federal Health Care Program. No safe harbor protected these commission payments, which constituted illegal remuneration under the AKS. On information and belief, Methodist agreed with RTA, LEROS, PET-CT and the Individual

Defendants to submit and cause the submission of claims for radiosurgery procedures that arose from this illegal financial arrangement.

60. All claims to Medicare and Medicaid arising from this unlawful financial arrangement were false claims under the FCA by operation of law. *See* 42 U.S.C. § 1320a-7b(g) (any claim that includes items or services resulting from a violation of the Anti-Kickback Statute is automatically a false claim for purposes of the False Claims Act). Such claims also contained both express and implied false certifications of compliance with the AKS, rendering them false claims under the FCA for these reasons as well. The CMS-1500 claim form contains an express certification of compliance with the AKS; the claim certification statement accompanying Medicaid claims certifies compliance with all rules, regulations and policies of DOH, which exclude from coverage services that are "fraudulently claimed." Further, in submitting claims to the Medicare and Medicaid programs for services related to illegally referred radiosurgery patients, Methodist and the other Defendants knowingly concealed the fact that those claims were not reimbursable because they arose from violations of the AKS. Compliance with the requirements of the AKS was indisputably a condition of payment and highly material to the government's decision to pay these claims. Accordingly, all claims submitted and caused to be submitted by the Defendants to Medicare and Medicaid that arose from these undisclosed and illegal patient referrals were false claims under the FCA, Moreover, all amounts received and converted by Defendants as a result of these fraudulent claim submissions after the effective date of the Patient Protection and Affordable Care Act ("PPACA") on March 23, 2010, represented "overpayments" that were never repaid and that therefore became "false claims" by operation of law within the meaning of the FCA and PPACA. 31 U.S.C. § 3729(b)(3); 42 U.S.C. § 1320a-

7k(d). As a consequence of this fraudulent scheme, the United States and New York State suffered substantial losses in an amount to be proven at trial.

C. The Fraudulent Scheme to Submit Claims for Unsupervised Imaging and Radiation Therapy Services

61. A third fraudulent scheme involved the provision and billing of unsupervised radiation oncology imaging and therapy services at LEROS. Medicare and Medicaid billing rules required, for the protection of the patient and as a condition of payment, that radiation oncology imaging and therapy services be directly supervised by a physician. Direct supervision required that the physician be in the office suite and immediately available to provide assistance and direction throughout the performance of the procedure. *See* Medicare Benefit Policy Manual, Chapter 15, Section 90; 42 CFR § 410.32(b)(3)(ii). Radiation oncology services which are not supervised by a physician are not "reasonable and necessary" and thus not reimbursable. *See* 42 CFR § 410.32(b)(1) ("Services furnished without the required level of supervision are not reasonable and necessary . . . ."); 42 CFR § 411.15(k)(1) (excluding from coverage services that are not reasonable and necessary for diagnosis or treatment).

62. At LEROS, radiation oncology services frequently were rendered without any physician supervision at all. These services included, on information and belief, radiation simulation, calculation of radiation dose, radiation treatment delivery and devices, intensity-modulated radiation therapy and CT scan guidance for insertion of radiation therapy fields. This absence of physician oversight created obvious health risks to patients, who effectively were at the mercy of the non-physician technologists operating the equipment. On occasion, incidents requiring physician oversight and involvement would occur with no physician on-site to intercede or assist.

63. LEROS business records document one instance in 2007 in which a patient who was

at LEROS for radiation therapy collapsed and was taken away by ambulance with no physician present at LEROS during the event, a fact that the medic who accompanied the ambulance specifically noted. The LEROS business record describing the incident took the form of a memo from Defendant Rafla titled "Confidential Occurrences" and announced the implementation of corrective measures ostensibly intended to ensure physician coverage at LEROS. Defendant Rafla further commented: "We do not want to have a reputation that therapists treat our patients and we are casual in covering the practice . . . ***We do not want billing questioned on the basis of absence of physicians***. . . I know that some of the above arrangements may be onerous or time wasteful but ***caution is much better and safer than trying to solve a problem posthumously.***" (emphasis added). Notwithstanding this memo, however, and despite the explicit recognition by Defendant Rafla that physician supervision was a condition of payment and that the lack of such supervision posed grave risks for patients, the absence of physician supervision persisted at LEROS and continued through at least in or about 2016.

64. On the subject of physician supervision at LEROS, Person A had conversations with radiation oncology residents who had done rotations at LEROS, which confirmed the lack of supervision. These residents commented, in words or substance, that "LEROS is a joke," "there is no one at LEROS on days doctors are supposed to be there – they stroll in at 1:30pm to 2:00pm and finish at 3:30pm," and "this is a mafia." When Person A commented that there must be someone there for the radiation therapy, the residents replied, in substance, that RTA had been acting in this fashion for years, that the absence of supervision was nothing new and that the Individual Defendants obviously knew about it, but did not care, since, for them, everything came down to financial considerations. Person A subsequently began paying attention to the LEROS coverage schedule and, after comparing the schedule to where the covering physicians

actually were at those times, Person A realized that the comments of the residents had been accurate, and that LEROS frequently lacked any physician supervision at all. Further, Person A knows that there were weekly meetings at RTA, at which all physicians were present (except for Defendant Tchelebi, who was located at Wyckoff Heights Medical Center), and when no physicians would have been present at LEROS. Additionally, when two RTA physicians were on vacation at the same time, there frequently would be no physician coverage at LEROS.

65. In submitting and causing the submission of claims to the Medicare and Medicaid programs, the Defendants knowingly concealed the fact that those claims were not reimbursable because they arose from the performance of radiation oncology services in the absence of physician supervision. Compliance with that supervision requirement was a condition of payment and highly material to the government's decision to reimburse. Had the government been aware of the lack of physician supervision, it certainly would not have paid these claims. All such claims submitted and caused to be submitted by the Defendants to Medicare and Medicaid, arising from the performance of radiation oncology services that were not supervised by physicians, were false claims under the FCA. Moreover, all amounts received and converted by Defendants as a result of these fraudulent claim submissions after the effective date of the Patient Protection and Affordable Care Act ("PPACA") on March 23, 2010, represented "overpayments" that were never repaid and that therefore became "false claims" by operation of law within the meaning of the FCA and PPACA. 31 U.S.C. § 3729(b)(3); 42 U.S.C. § 1320a-7k(d). As a consequence of this fraudulent scheme, the United States and New York State suffered substantial losses in an amount to be proven at trial.

D. The Fraudulent Scheme to Submit Claims for Imaging and Radiation Therapy Services Not Rendered

66. A fourth fraudulent scheme involved the billing of radiation oncology imaging

and therapy services that were not actually performed. As explained above, Image Guided Radiation Therapy, or IGRT, is a form of radiation therapy that utilizes imaging techniques during each treatment session in order to ensure that the radiation is narrowly focused on the intended treatment area. These images may be captured with CT technology. IGRT is used in conjunction with IMRT in patients who may have malignant tumors that are located near or within critical body parts or where more precision is required. Some CPT codes that are used to bill this procedure include **76950** (Ultrasonic guidance for placement of radiation therapy fields); **77014** (Computed tomography guidance for placement of radiation fields); **77421** (Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy); **0197T** (Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (eg, 3D positional tracking, gating, 3D surface tracking), each fraction of treatment); **77418** (Intensity Modulated Radiation Therapy (IMRT) delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session).

67. The Individual Defendants, however, frequently failed to review those images in advance of the radiation therapy performed on their patients. Since the purpose of capturing the images is to assist the physician in focusing the radiation therapy on the intended treatment area, not reviewing the images in advance defeats the purpose of this particular kind of radiation therapy by effectively dispensing with the "image guided" portion of the service. In these circumstances, the imaging services performed and billed cannot be deemed "medically necessary." Even when images were read, they were often read by unlicensed radiation oncology residents without physician supervision. Claiming reimbursement for imaging services that were

not read, or that were read by unsupervised, unlicensed residents, would be tantamount to billing for services not rendered or worthless services.

68. In reference to checking films, Person A overheard discussions between Defendant Ashamalla and Defendant Mohktar, who stated on multiple occasions that "I don't do that," referring to the review of CT images. Defendant Mohktar would walk away and say "tsou tsou [*i.e.,* no, no]" while shaking his head, leaving Defendant Ashamalla standing there laughing. Defendant Ashamalla would sometimes add a comment that "Dr. Mohktar doesn't like and believe in films." Defendant Ashamalla, however, also did not review CT images. Person A reviewed films with residents after starting work at RTA, but found that both Defendant Ashamalla and Defendant Mohktar did not do the same and believed it was not necessary. At a meeting of physicians and staff held in the spring of 2016, Defendant Ashamalla stated, "If they ever audit us on imaging, we will get into trouble," and smiled.

69. Similarly, on multiple occasions, Defendant Ashamalla performed brachytherapy on prostate cancer patients that was so deficient as to constitute a worthless service and/or a service not rendered. As previously explained, brachytherapy for prostate cancer is a procedure involving the placement of radioactive seeds in the prostate gland to treat the cancer. On multiple occasions, Defendant Ashamalla improperly performed this procedure by implanting the radioactive seeds either entirely or partially outside the prostate gland and inside the rectum. As a consequence, the cancer treatment rendered ranged from non-therapeutic to sub-therapeutic, thereby imperiling the health and the lives of his patients. Defendant was aware that the "treatment" was deficient and concealed that fact from patients. On information and belief, however, Defendant billed or caused the billing of these defective services to payers anyway, including to Medicare and Medicaid. Some CPT codes that are used to bill this procedure

include **77778** (Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed) and **55875** (Transperineal placement of needles or catheters into prostate for interstitial radio element application, with or without cystoscopy). Defendant, moreover, failed to comply with federal and state laws requiring that he report the misadministration of radiation to the government and to the patients who received deficient (*i.e.*, non-therapeutic or sub-therapeutic) treatment. *See* 10 N.Y.C.R.R. § 16.25; 10 C.F.R. § 35.3045; New York City Health Code, Article 175.

70. By knowingly submitting and causing the submission of claims to Medicare and Medicaid for: (1) imaging services purportedly included as part of IGRT in order to guide radiation therapy (including "CT scan guidance for insertion of radiation therapy fields" and "X-ray guidance for radiation therapy delivery") despite the fact that the images captured were not reviewed before administering radiation therapy; and (2) brachytherapy services for prostate cancer patients, where the defective implantation of radioactive seeds outside the prostate resulted in non-therapeutic or sub-therapeutic treatment, Defendants billed the government for worthless services and/or services not rendered, in violation of the FCA and NYFCA.

71. All such claims were factually false because they did not accurately describe the imaging and therapy services that were actually performed. All such claims also were legally false because the certifications of truth and accuracy accompanying each claim, including that the services were medically necessary, were false. Moreover, all amounts received and converted by Defendants as a result of these fraudulent claim submissions after the effective date of the Patient Protection and Affordable Care Act ("PPACA") on March 23, 2010, represented "overpayments" that were never repaid and that therefore became "false claims" by operation of law within the meaning of the FCA and PPACA. 31 U.S.C. § 3729(b)(3); 42 U.S.C. § 1320a-

7k(d). As a consequence of this fraudulent scheme, the United States and New York State have suffered substantial losses in an amount to be proven at trial.

VI. CAUSES OF ACTION

COUNT ONE
(Federal False Claims Act)
31 U.S.C. § 3729(a)(1)(A)

72. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 71 above as though fully set forth herein.

73. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended.

74. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States government for payment or approval. 31 U.S.C. § 3729(a)(1)(A).

75. The United States, unaware of the falsity of the claims made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

76. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

77. Additionally, the United States is entitled to the maximum penalty of $11,000 (and up to $21,563 per claim for claims made after November 2, 2015) for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT TWO
(Federal False Claims Act)
31 U.S.C. § 3729(a)(1)(B)

78. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 71 above as though fully set forth herein.

79. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended.

80. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted facts, that were material to false or fraudulent claims, within the meaning of 31 U.S.C. § 3729(a)(1)(B).

81. The United States, unaware of the falsity of the records, statements and material omissions made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

82. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

83. Additionally, the United States is entitled to the maximum penalty of $11,000 (and up to $21,563 per claim for claims made after November 2, 2015) for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT THREE
(Federal False Claims Act)
31 U.S.C. § 3729(a)(1)(G)

84. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 71 above as though fully set forth herein.

85. This is a claim for treble damages and penalties under the False Claims Act, 31

U.S.C. §§ 3729, *et seq.*, as amended.

86. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government, within the meaning of 31 U.S.C. § 3729(a)(1)(G).

87. The United States, unaware of the falsity of the records and statements and of the Defendants' concealment and unlawful conduct, was denied an opportunity to claim and demand return of the money and property to which it was legally entitled.

88. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

89. Additionally, the United States is entitled to the maximum penalty of $11,000 (and up to $21,563 per claim for claims made after November 2, 2015) for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT FOUR
(Federal False Claims Act)
31 U.S.C. § 3729(a)(1)(C)

90. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 71 above as though fully set forth herein.

91. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended.

92. By virtue of the acts described above, Defendants conspired with each other and

with others unknown to defraud the United States by inducing the United States to pay or approve false and fraudulent claims, and to avoid and conceal an obligation to pay money and property, within the meaning of 31 U.S.C. § 3729(a)(1)(C). Defendants, moreover, took substantial steps in furtherance of the conspiracy, *inter alia*, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts.

93. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

94. Additionally, the United States is entitled to the maximum penalty of $11,000 (and up to $21,563 per claim for claims made after November 2, 2015) for each and every violation of 31 U.S.C. § 3729(a)(1)(C) as described herein.

COUNT FIVE
(New York False Claims Act)
N.Y. Finance Law § 189(1)(a)

95. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 71 above as though fully set forth herein.

96. This is a claim for treble damages and penalties under the New York False Claims Act, N.Y. Finance Law §§ 187, *et seq.*, as amended.

97. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to New York State for payment or approval, within the meaning of N.Y. Finance Law § 189(1)(a).

98. New York State, unaware of the falsity of the claims made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

99. By reason of the Defendants' acts, New York State has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

100. Additionally, New York State is entitled to the maximum penalty of $12,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT SIX
(New York False Claims Act)
N.Y. Finance Law § 189(1)(b)

101. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 71 above as though fully set forth herein.

102. This is a claim for treble damages and penalties under the New York False Claims Act, N.Y. Finance Law §§ 187, *et seq.*, as amended.

103. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted facts, material to false or fraudulent claims, within the meaning of N.Y. Finance Law § 189(1)(b).

104. New York State, unaware of the falsity of the records, statements and material omissions made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

105. By reason of the Defendants' acts, New York State has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

106. Additionally, New York State is entitled to the maximum penalty of $12,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT SEVEN
(New York False Claims Act)
N.Y. Finance Law § 189(1)(g)

107. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 71 above as though fully set forth herein.

108. This is a claim for treble damages and penalties under the New York False Claims Act, N.Y. Finance Law §§ 187, *et seq.*, as amended.

109. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government, within the meaning of N.Y. Finance Law § 189(1)(g).

110. New York State, unaware of the falsity of the records and statements and of the Defendants' concealment and unlawful conduct, was denied an opportunity to claim and demand return of the money and property to which it was legally entitled.

111. By reason of the Defendants' acts, New York State has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

112. Additionally, New York State is entitled to the maximum penalty of $12,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT EIGHT
(New York False Claims Act)
N.Y. Finance Law § 189(1)(c)

113. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 71 above as though fully set forth herein.

114. This is a claim for treble damages and penalties under the New York False Claims Act, N.Y. Finance Law §§ 187, *et seq.*, as amended.

115. By virtue of the acts described above, Defendants conspired with each other and with others unknown to defraud New York State by inducing New York State to pay or approve false and fraudulent claims, and to avoid and conceal an obligation to pay money and property, within the meaning of NY Finance Law § 189(1)(c). Defendants, moreover, took substantial steps in furtherance of the conspiracy, inter alia, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts.

116. By reason of the Defendants' acts, New York State has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

117. Additionally, New York State is entitled to the maximum penalty of $12,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

PRAYER FOR RELIEF

WHEREFORE, Relator, acting on behalf and in the name of the United States of America and New York State, demands and prays that judgment be entered against Defendants under the Federal False Claims Act and New York False Claims Act as follows:

(1) That Defendants cease and desist from violating 31 U.S.C. §§ 3729 *et seq.* and N.Y. Finance Law §§ 187, *et seq.* as set forth above;

(2) That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 (and not less than $10,781

and not more than $21,563 per claim for claims made after November 2, 2015) for each violation of 31 U.S.C. § 3729;

(3) That this Court enter judgment against Defendants in an amount equal to three times the amount of damages that New York State has sustained because of defendants' actions, plus a civil penalty of not less than $6,000 and not more than $12,000 for each violation of N.Y. Finance Law §§ 187, *et seq.*;

(4) That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and N.Y. Finance Law § 190;

(5) That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

(6) That Relator recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: October 31, 2017

By: _____

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